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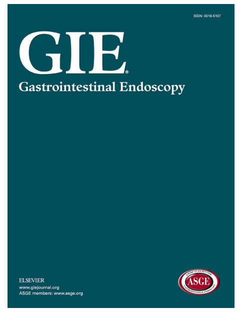

Risk-based Decision Making Related to Pre-Procedural-COVID-19 Testing in the Setting of Gastrointestinal Endoscopy: Management of Risks, Evidence, and Behavioral Health Economics

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Author Contributions

All authors conceived and designed the study and reviewed the literature. AS and GH designed and conducted the scoping review within the study. All authors reviewed the scoping review and underlying data. NM, UD, AS and GH wrote the first draft of the manuscript. All authors agreed on the content of and critically revised the manuscript. All authors gave final approval of the version to be published. All authors had full access to all the data and had final responsibility for the decision to submit for publication.

Declaration of interests

NJT reports, non-financial support from HVN National Science Challenge NZ, personal fees from Aviro Health (Digestive health) (2019), Anatara Life Sciences, Brisbane (2019), Allakos (gastric eosinophilic disease) (2021), Bayer [IBS] (2020), Planet Innovation (Gas capsule IBS) (2020), Takeda, Japan (gastroparesis) (2019), twoXAR (2019) (IBS drugs), Viscera Labs, (USA 2021) (IBS-diarrhoea), Dr Falk Pharma (2020) (EoE), Censa, Wellesley MA USA

(2019) (Diabetic gastroparesis), Cadila PharmIncaceuticals (CME) (2019), Progenity Inc. San Diego, (USA 2019) (Intestinal capsule), Sanofi-aventis, Sydney (2019) (Probiotic), Glutagen (2020) (Celiac disease), ARENA Pharmaceuticals (2019) (Abdominal pain), IsoThrive (2021) (oesophageal microbiome), BluMaiden (2021), Rose Pharma (2021), Intrinsic Medicine (2021), Comvita Mānuka Honey (2021) outside the submitted work; In addition, NJT has a patent Nepean Dyspepsia Index (NDI) 1998, Biomarkers of IBS licensed, a patent Licensing Questionnaires Talley Bowel Disease Questionnaire licensed to Mayo/Talley, a patent Nestec European Patent licensed, and a patent Singapore Provisional Patent “Microbiota Modulation Of BDNF Tissue Repair Pathway” issued, “Diagnostic marker for functional gastrointestinal disorders” Australian Provisional Patent Application 2021901692. Committees: OzSage, Australian Medical Council (AMC) [Council Member]; Australian Telehealth Integration Programme; MBS Review Taskforce; NHMRC Principal Committee (Research Committee) Asia Pacific Association of Medical Journal Editors. Boards: GESA Board Member, Sax Institute, Committees of the Presidents of Medical Colleges. Community group: Advisory Board, IFFGD (International Foundation for Functional GI Disorders), AusEE. Miscellaneous: Avant Foundation (judging of research grants). Editorial: Medical Journal of Australia (Editor in Chief), Up to Date (Section Editor), Precision and Future Medicine, Sungkyunkwan University School of Medicine, South Korea, Med (Journal of Cell Press). NJT is supported by funding from the National Health and Medical Research Council (NHMRC) to the Centre for Research Excellence in Digestive Health and he holds an NHMRC Investigator grant.

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Risk-based Decision Making Related to Pre-Procedural-COVID-19 Testing in the Setting of Gastrointestinal Endoscopy: Management of Risks, Evidence, and Behavioral Health Economics

Background and Aims: Controversies exist in relation to the benefits and the most appropriate approach for pre-procedural COVID-19 testing (e.g., Rapid Antigen Test (RAT) or Polymerase Chain Reaction (PCR) or real time Polymerase Chain Reaction (RT-PCR)) for outpatients undergoing diagnostic and therapeutic procedures, such as gastrointestinal endoscopy, to prevent COVID-19 infections among staff. Guidelines for protecting health care workers (HCW) from SARS-CoV-2 infection via outpatient procedures varies across medical professional organizations. This study provides an evidence-based decision support tool for key decision-makers (e.g., clinicians) to respond to COVID-19 transmission risks and reduce the effect of personal biases.

Methods: A scoping review was used to identify relevant factors influencing COVID-19 transmission risk relevant for gastrointestinal endoscopy. From 12 relevant publications, eight factors were applicable: test sensitivity, prevalence of SARS-CoV-2 in the population, age adjusted SARS-CoV-2 prevalence in the patient cohort, proportion of asymptomatic patients, risk of transmission from asymptomatic carriers, risk reduction by Personal Protective Equipment (PPE), vaccination rates of HCW. The probability of a serious adverse event (SAE), such as workplace acquired infection resulting in HCW death, under various scenarios with pre-procedural testing is determined and informs decision makers of expected costs of reductions in SAEs.

Results: In a setting of high community transmission, without testing and PPE, 117·5 SAE per million procedures would occur and this is reduced to between 0·079 to 2·35 SAE per million procedures with use of PPE and pre-procedural testing. Utilising these variables and testing a range of scenarios the probability of an SAE is low even without testing but is reduced by pre-procedural testing.

Conclusions: Under all scenarios tested, pre-procedural testing reduces the SAE risk for HCW regardless of the SARS-CoV-2 variant. Benefits of pre-procedural testing are marginal when community transmission is low (e.g., below 10 infections/day/100,000 population). The proposed decision support tool can assist to develop rational pre-procedural testing policies.

Background

At the beginning of the COVID-19 pandemic and subsequent surges, many high-volume clinical diagnostic and therapeutic services were restricted to urgent cases. This was due to the need to divert resources towards the care of COVID-19 patients and a result of concerns regarding the spread of COVID-19 infections among clinical staff.[1,2] In the context of endoscopy, it has been recognised that reduced capacity for endoscopic services have resulted in an increased rate of adverse outcomes related to delayed treatment of cancers and other conditions.[3] In most jurisdictions endoscopic services have resumed while the COVID-19 pandemic/endemic persists, and services are forced to transition to a new normal [4] with added complexities to manage COVID-19 related risks for patients and staff. Evidence suggests that with appropriate precautions the risk to staff becoming infected with COVID-19 during an endoscopic procedure is limited.[5]

Occupational health and safety is a concern amongst healthcare workers (HCW), which requires attention when providing clinical services in the setting of a pandemic. Data from the early phase of the pandemic suggests a low but appreciable risk of SARS-CoV-2 transmission for HCW and patients in the setting of gastrointestinal endoscopy.[5,6] Besides appropriate vaccination of all HCW, a variety of measures are suitable to mitigate the infection risk, which includes the use of appropriate personal protective equipment (PPE) such as KN95 masks, staff limits in procedure rooms, screening patients for potential COVID-19 symptoms and postponing/testing patients with symptoms, testing of all patients or discontinuation of services.[7] Considering the importance of avoiding delays in treatment of relevant conditions such as GI cancers [8], endoscopic services have re-started worldwide.

Guidelines from professional organisations, however, recommended different approaches. The most recent guideline from the American Gastroenterological Association favours screening of all elective endoscopy patients for potential COVID-19 related symptoms and testing of symptomatic patients (e.g., with Polymerase Chain Reaction (PCR) or Reverse Transcription-PCR (RT-PCR)) while no testing is recommended for asymptomatic patients.[9] This is based upon low transmission rates reported from endoscopy settings and assumes use of appropriate PPE with N95 masks.[5,10] In contrast, the European Society for Gastrointestinal Endoscopy (ESGE) recommend patients undergoing gastrointestinal endoscopy should be fully vaccinated or have a negative PCR-test [7] while the use of rapid antigen testing (RAT) was not recommended. Irrespective of these guidelines, many HCW prefer pre-procedural COVID-19 screening with RAT or PCR in all patients to minimise personal exposure risks.

Choice of an appropriate risk mitigation during the COVID-19 pandemic/endemic is based upon a variety of factors, however it is a decision that is chosen under uncertainty. The limitations facing decision makers in the context of complex decision making are well established.[11] The decisions are not only relevant because resource allocation for specific risk-mitigation measures should result in relevant and cost-efficient reduction of risks, but some risk mitigation measures may increase morbidity and mortality. This is further complicated by a variety of rapidly changing factors including the prevalence of community infection, vaccination rates and the efficiency of available vaccines in relation to the prevention of SARS-CoV-2 transmission and complications. The COVID-19 pandemic provides a challenge for health systems and necessitates the modification or redesign of clinical practice. Changes in practice should be based on clinical judgement, available evidence, and the balance of probabilities that a measure achieves the intended outcome.[12] In the rapidly changing environment, a new level of evidence-based medicine is urgently required that allows key decision-makers (e.g., clinicians) to respond with agility but without personal biases.

We outline a decision tool that can be used to inform on choices of testing or not, enabling decision makers to consider the estimated financial cost per expected serious adverse event (SAE), which we define as a workplace acquired infection with subsequent death of a HCW. We argue this financial cost is like the value used to justify decisions for funding of new therapies or procedures in relation to adding a QALY - a quality adjusted life year, which is a measure of that combines the length of life with the quality of life.[13] For discussion we illustrate the argument of an SAE as equivalent to the loss of one QALY. As with all choices, decision makers may differ with respect to these and other judgements based on the parameters they observe, our decision support tool expands existing literature by allowing decision makers to choose their own parameters to inform their decisions on pre-procedural asymptomatic testing. This approach may not only be suitable to determine the benefit of pre-procedural testing versus not testing in various scenarios but could allow the appropriate time-point to discontinue pre-procedural testing when community transmission decreases, in line with observations in Ebigbo, Römmele.[14]

Material and methods

To determine the factors that influence the risk of an SAE, we conducted a scoping review which is a map of synthesised research on a particular topic[15]. We performed an electronic database search of MEDLINE and EMBASE, using the search terms in Appendix 1 which were searched for peer-reviewed publications up until January 2022 for original studies providing information related to risk of COVID-19 and endoscopic services. It was restricted to English and German articles, involving humans. Articles were excluded if they did not involve a gastrointestinal procedure, HCW and COVID-19 transmission. We identified 588 publications (see Appendix 2), which returned several of the following themes surrounding risk factors for SARS-CoV-2 transmission. After discussion with clinicians, we identified an additional theme - risk modifier in the patient population. IRB approval and patient consent were not required for this study.

SARS-CoV-2 Transmission Risk Factors:

Sensitivity of the screening test: the ability of screening tests to correctly identify asymptomatic carriers of disease is highly variable with PCR the gold standard.[16-18] Lower sensitivity rates for RAT kits have been observed in clinical setting, with one indicating a 65% clinical sensitivity.[19] This sensitivity varies further when comparing asymptomatic to symptomatic patients (63% vs. 89%).[20]

Population prevalence of SARS-CoV-2 infections in the respective area: The prevalence of COVID-19 infections in the population greatly influences the probability that a patient referred for a procedure is COVID-19 positive.[1]

Risk modifier for the a priori risk of a SARS-CoV-2 infection in the referral population: The risk of infection is influenced by sociodemographic factors.[21] In a setting were a large proportion of the population is vaccinated (e.g., 80-90%), the infection risk is usually highest in people below 40,[22] as such if the majority of endoscopy patients is above 50 and below 85 years of age and the risk of infection is lower.

Proportion of asymptomatic SARS-CoV-2 carriers: A proportion of infected subjects is initially or for the whole course of the infection asymptomatic.[23-25] This proportion increases in vaccinated subjects.[26]

Transmission rates from asymptomatic carriers: The risk to transmit a SARS-CoV-2 infection is related to the symptom status since asymptomatic carriers have a lower viral load.[23] With the variation in test sensitivity, the possibility of a false negative result exists for asymptomatic patients.[24]

Risk of transmission in the setting of GI endoscopy with appropriate PPE: The use of PPE is highly recommended to reduce the transmission of COVID-19 in endoscopy procedures.[1,17,27-29] The risk of transmission from an asymptomatic carrier to appropriately protected staff with N95 masks is low.[6] While there are good data supporting the efficacy of surgical and cloth masks in preventing COVID-19 infections in the community setting, there are limited data on the efficacy of surgical masks to prevent infections of exposed HCW in the clinical setting.[30]

Risk reduction of infection by vaccination: Vaccinations have been proven to reduce the risk of contracting SARS-CoV-2**.**[27] For those HCW that are vaccinated, there is a >90% reduction in the risk of a SARS-CoV-2 infection.[31] The risk reduction will differ based on the SARS-CoV-2 variant, which have different levels of transmissability.[32]

Risk reduction of SAE by vaccination: There is a reduced risk of an SAE in vaccinated HCW.[27] For a vaccinated individual, there is a 70-78% reduction in the risk of an SAE, in terms of mortality.[31,33]

Decision-Making Tool Comparing Test Sensitivities

To understand the risk and impact of SARS-CoV-2 infection for staff providing endoscopic services with or without pre-procedural testing, we calculated the risk of a SAE in a HCW based on probabilities related to SARS-CoV-2 transmission and community infection in Australia. Given the small probabilities, we present estimates of the risk per one million endoscopy procedures. We consider factors identified in the scoping review.

Currently some guidelines recommend the use of RAT and/or PCR testing to asymptomatic patients, as such we examine the probability of a SAE of a HCW under several scenarios: (1) no testing no PPE and high community transmission; (2) worst case RAT: low test sensitivity and high community transmission; (3) best case RAT: high test sensitivity and low community transmission, (4) worst case PCR: high community transmission; (5) best case PCR: low community transmission, and (5) an alternate scenario faced by governments at the beginning of the pandemic: PCR test, low community transmission and no PPE. Only scenarios 2-4 use PPE and this is classified as the use of N95 masks.

The scenarios explore the effects of the variation in RAT sensitivity rates, baseline risk of an SAE, and the availability of PPE when testing asymptomatic patients. For the PCR, we use a 95% sensitivity. While the sensitivity of RAT is based on the Australian Therapeutic Goods Administration (TGA) recommendation of 90% sensitivity, we do not use the TGA's 95% recommendation as RAT kits do not have the same sensitivity as a PCR. In the worst case RAT scenario a sensitivity of 60% is used, due to RAT kits having a lower clinical sensitivity for asymptomatic patients.[20,34] Similarly, we consider the situation of community prevalence of COVID-19 over a range of 1·36%-20·36%. In terms of risk reduction due to vaccination, we vary the risk of an SAE at 20%, 30% and 40%, by doing so we can vary the risk of an SAE for SARS-CoV-2 variants.

We calculated the probability of a SAE based on the aforementioned factors under different scenarios and used this to determine the cost to avoid a SAE in a HCW for a million procedures with ten staff exposed per endoscopy procedure (for the calculation see Appendix 3). For our calculations, the cost of a RAT is $10, and a PCR is $100.

The initial model was stress tested with a variety of scenarios [35] and reviewed to develop a final model. Stress testing the model with a variety of extreme assumptions (see Appendix 4, Figure A1 and A2), revealed that the risk of SAE for staff involved in the delivery of endoscopic services is incredibly low and likely smaller than the risk associated with SARS-CoV-2 exposure in daily life (e.g., dining at a restaurant [36]). Nevertheless, preprocedural testing had a protective effect. Thus, the cost-benefit analysis in relation to SAEs avoided can be assessed. A QALY can be used as a benchmark to determine the efficient and effective testing recommendation. As there is no official threshold in Australia, we use a benchmark of AUD$28,000 to AUD$50,000 per SAE avoided to be recommended as cost effective.[37-39]

The role of the funding source

There was no funding source for this study.

Results

The costs and benefits of testing

When comparing the risk of an adverse outcome of a HCW between no asymptomatic testing vs. RAT testing (with variable RAT sensitivities) or PCR testing for a million endoscopic procedures, the occurrence of an SAE is less than one in a million procedures when community transmission is low for RAT screening, or PPE and PCR testing are used (Table 1). The worst-case RAT scenario had an expected occurrence of 2·35 SAE in a million procedures involving 10 staff members during every procedure (e.g., staff in the procedure room, recovery staff). Whilst the lowest number of expected SAE (N = 0·079) was in the best-case PCR scenario, the value of using PPE is demonstrated when comparing the occurrence of an SAE in the alternate strategy and best-case PCR scenario, with the SAE per million procedures reducing from 1·59 to 0·079, respectively.

The direct cost of pre-procedural COVID-19 testing in endoscopic patients will vary based on the current level of transmission amongst the community and patient population (see Figure 1). When considering higher community infections rates with subsequent high transmission rates (e.g., 18·3% community transmission) in non-health care environments, the cost to avoid one SAE using RAT with 60% sensitivity is $86,838·41 at 5% community transmission when compared to a no testing strategy. This cost remains above the Australian benchmark of AUD$28,000 for mortality-related QALY gained - $50,000 per QALY for pharmaceuticals, however as the level of community transmission increases the cost to avoid an SAE will reduce to below the benchmark (see Figure 1). In the case a pre-procedural PCR, the cost of avoiding an SAE remains greater than the benchmark no matter the rate of community transmission when PCR tests are $100.

We observe that at any rate of transmission in the community and patient population the probability of an SAE, a no testing strategy using PPE would be more cost effective than testing when no PPE is used regardless of test sensitivity level, community transmission and the risk of a SAE or infection of a vaccinated HCW in comparison to no testing. In the case of a 5% level of transmission, when no testing occurs but PPE is used, there is a P(SAE) = 5·8753E-07. Despite the variation in probabilities of a SAE, when we make decisions on who should have testing, we must consider the opportunity costs to the allocation of testing resources and the opportunity cost of the financial resource allocation. The decision tool, which is a template of the calculations described above has been made available (see supplementary material).

Opportunity costs of testing

Screening for COVID-19 is an essential health provision when infections are rising. However, this screening is constrained by the health systems resources to facilitate the demand for testing. The supply of PCRs is restricted by laboratory capacity and RAT by supply, and in periods of high demand, the infrastructure for testing is unable to meet demand. As such, specific decisions on who and when individuals are required to be tested are made, often with the intention of reducing transmission for target groups. The criteria for those who are eligible for testing does come with trade-offs.

If there are no constraints on the availability of RAT or PCR, then the test with the greatest sensitivity is the optimal choice. At current levels of RAT sensitivity, it is likely that if pre-procedural testing for asymptomatic patients is conducted, PCR testing outperforms RAT. However, this assumption of greater test sensitivity is limited as we assume a negative PCR 3-days to 24-hours before the procedure implies that there is no risk of infecting others during the procedure. In our tool, the reliability of PCR testing can be adjusted to accommodate the risk of infection within the usual delay of PCR tests available and the risk of becoming infected between test and procedure - which could change the choice of RAT vs PCR tests.

Finally, when community transmission is high the direct opportunity cost of not conducting a procedure due to a positive pre-procedural test result should be considered. While it is established that 2020 closures of screening procedures are associated with adverse health impacts due to delayed diagnosis of e.g. colon cancers[40], we should consider positive test reduces capacity to provide endoscopies and furthers health costs due to delayed screening procedures.

Discussion

The COVD-19 pandemic necessecitates decisions in a rapidly changing environment. For example, there is the use of pre-procedural testing to mitigate the risk of SARS-CoV-2 infections in HCW. This choice to screen or not creates a challenging set of decisions for standard medical testing and screening procedures, such as colon cancer screening procedures conducted in Endoscopy Departments. Given many of these decisions involve uncertainty, caused by small probabilities, decision makers are highly likely to be affected by cognitive biases. The calculations and simulations we have provided in this tool, aim to enable clinicians to consider relevant factors, and facilitates the comparison of choices for COVID-19 testing and screening policies and adjust for changes of relevant parameters as they change over time.

Furthermore, this tool can be adapted for use in other settings, as the principle of the tool is to guide decision making. This tool is developed from a cost-effectiveness analysis, however instead of comparing between different testing strategies, the tool allows decision-makers to make an informed choice on the testing strategy based on the different sensitivities of testing strategies compared to no pre-procedural testing. The tool enables one to test a variety of scenarios and different types of SAE (e.g., hospitalization) using relevant information for their hospital, region and risk profile and inform their judgement on test reliability and costs. Thus enabling the decision maker to make a more evidence based decision - and less likely being affected by behavioural biases regarding underlying risks. Such a tool can be used to navigate through unknown situtations, thereby supporting the decision maker to achieve better outcomes, without affecting their ability to make the decision while taking other considerations - political, emotional, or organisational - into account.

Most practices have followed the guidelines set out by their respective professional association or societies, and stratify based upon sysmptoms which do not focus on asymptomatic patients. However, many clinicians still prefer pre-procedural COVID-19 screening for asymptomatic patients. The recommended use of pre-procedural RAT and PCR testing in endoscopic patients may be unnecessarily delaying procedures and diverting resources to activities with no or marginal benefits. This is an administrative decision that should be based on the characteristics of the underlying situation with respect to the risks, benefits and costs involved of testing for COVID-19. While some factors are inherently uncertain, we now have reasonably reliable data about the probabilities of COVID-19 infection and the risk of a SAE such as COVID-19 related death. Careful considerations of all these parameters should help to overcome potential risks of overweighting small probabilities and consequences to choose appropriate screening strategies.

We indicate that while direct costs of administering tests do seem high compared to other health expenditures - considering avoidance of SAE - once the potential opportunity costs are considered the recommended decision of testing asymptomatic patients may change. For instance, during a period of high rates of community infection, testing capacity may be limited. A test for asymptomatic patients that are due for an endoscopy may reduce the opportunity to test people who do not require an endoscopy with symptoms or other indications. Our arguments and the tool can provide the relevant information to make these decisions, while accounting for medical, administrative and political/social considerations. Hence, this tool focuses on the environmental factors and not the underlying cost of the different strategies (e.g., RAT vs. PCR).

When considering the opportunity cost the logic of testing changes, while under low community infection rates the cost per avoided SAE among staff is higher, but still within range compared to other health policy decisions, as there are few positive test results the effect of lost capacity is much lower as well. Once community infection rates are higher, testing significantly affects a hospital's ability to operate at capacity and the decision may change. Adding to that a potential shortage of test capacity within a health system may further weaken the case for a testing policy but would require the determination of where a health care resource in limited supply provides the greatest benefit. Furthermore, we did not differentiate for N95 or flat surgical masks since the guidelines of the ESGE did not assume a difference based upon a systematic review and meta-analysis[41]. Finally, the decision support tool can provide evidence to stick to or diverge from recommended guidelines. For example, the ESGE[7] recommend that no testing is provided to fully vaccinated individuals, by using the decision support tool a facility can determine the appropriate level of risk that they are willing to take if a vaccintated individual is asymptomatic. Especially if the opportunity cost of having staff on leave is greater in some areas then others (e.g., consider low- and middle-income countries). Similarly the guidelines from the American Gastroenterological Association[9] made a recommendation that routine preprocedure testing for SARS-CoV2 in patients scheduled to undergo endoscopy. While these experts placed a high value on minimizing additional delays in patient care and potential downstream effects in relation to delays of patient care, staff safety and the costs associated with preprocedural testing were not considered.

Howver, our approach with an adaptable decsion support tool is also not without limitations. We have specified the setting of endoscopic procedures, however the risk of tranmission was not broken down into an aerosol-generating versus a non-aerosol generating procedures. A breakdown of this risk will lead to a greater understanding of the specific risk of individual procedures, however at the current level the risk would be a slight overestimation. Moreover, most endoscopists would provide a mix of services and the available data do not allow to allocate different risks to lower or upper endoscopy. Additionally, our approach is focussed on the worst possible outcome (fatality) of a workplace related SARS-CoV-2 transmission of a HCW. Thus, we did not include other adverse effects of SARS-CoV-2 transmission such as sick leave of infected staff, impact on service capacity, hospitalization etc. Nor have we considered the death of a patient as the outcome of interest, as the majority focus of health department governmance has been protecting healthcare workers. Furthermore, we did not incorporate transactional costs to collect swabs or fluid samples for further testing, nor the burden of cancelled or missed procedures because of a patient positive COVID-19 test. We also did not consider the costs on the staffing capacity of the endoscopy unit if infection or a SAE does occur. If asymptomatic testing does not occur and a procedurally transmitted COVID-19 infection does occur, then HCW shortages will impact the capacity of the unit to provided services. Using such SAE is a reasonable simplification considering these costs (and benefits) are linear yet highly variable across systems and could be relatively easily incorporated in local modelling.

We did not incorporate the relevance of testing for the service delivery (e.g., additional resources required to perform the tests), including delay of services until the test results are available. Additionally, the possibility of false positives and negatives might alter decision-making and complicate the processes. On the other hand, the proposed approached provides a tool that allows the incorporation and adjustment for a multitude of factors to provide decision support. This tool is rapidly adoptable to inform choices by incorporating clinical judgement, available evidence, and the balance of probabilities of the intended outcome. Thus, the proposed decision tool provides support in a complex and potentially rapidly changing environments. Instead of proposing a specific measure (e.g., to use a specific test prior to endoscopic procedures), future guidelines could articulate the acceptable risk-level. This would provide a decision framework that avoids biases and allows rational allocation of resources to maximise benefits in relation to staff safety and patient outcomes.

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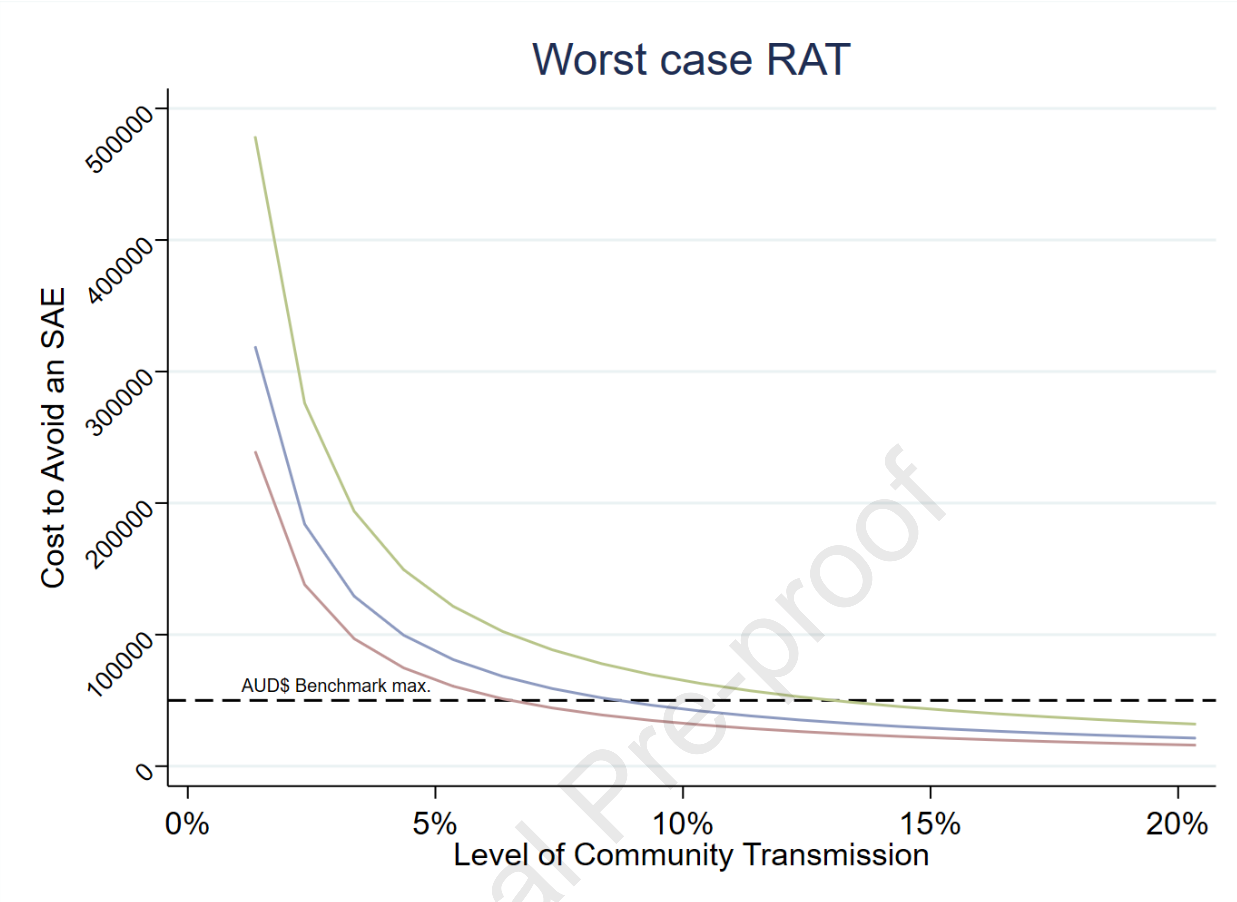
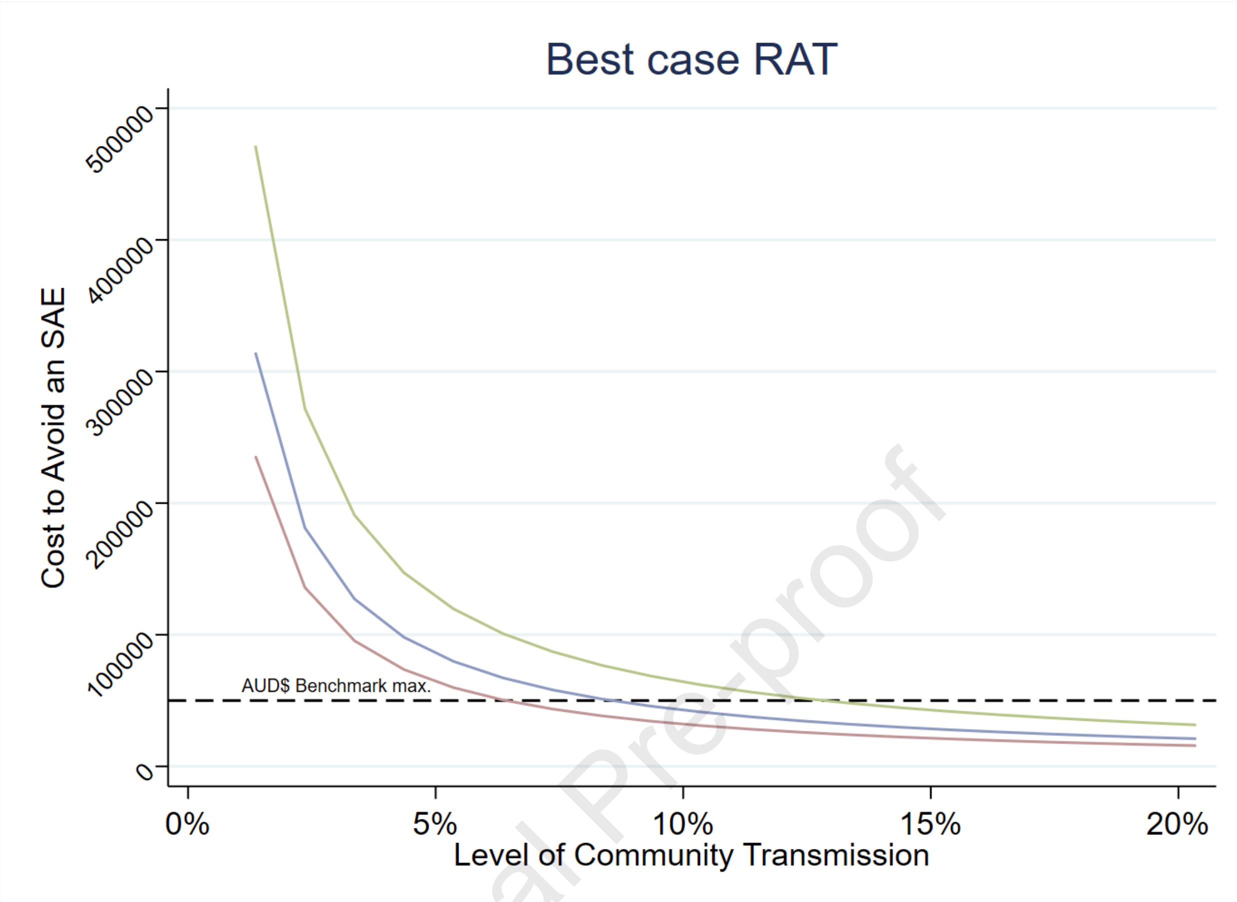
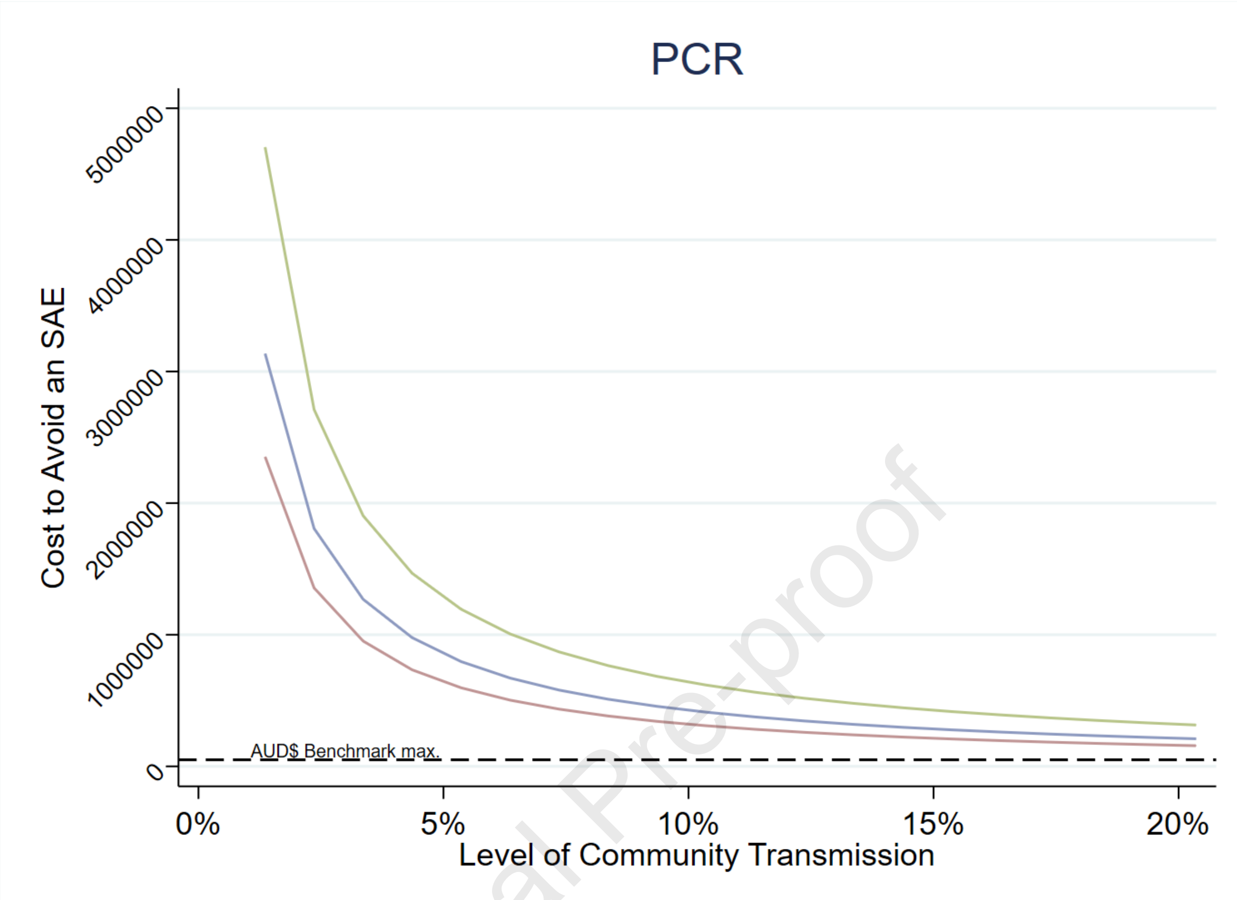
Figure 1, Legend: Blue line, Risk of SAE = 30%; Green line, Risk of SAE = 20%; Red line, Risk of SAE = 40%. Each figure represents the expected costs of testing asymptomatic patients under different levels of risk of an SAE.

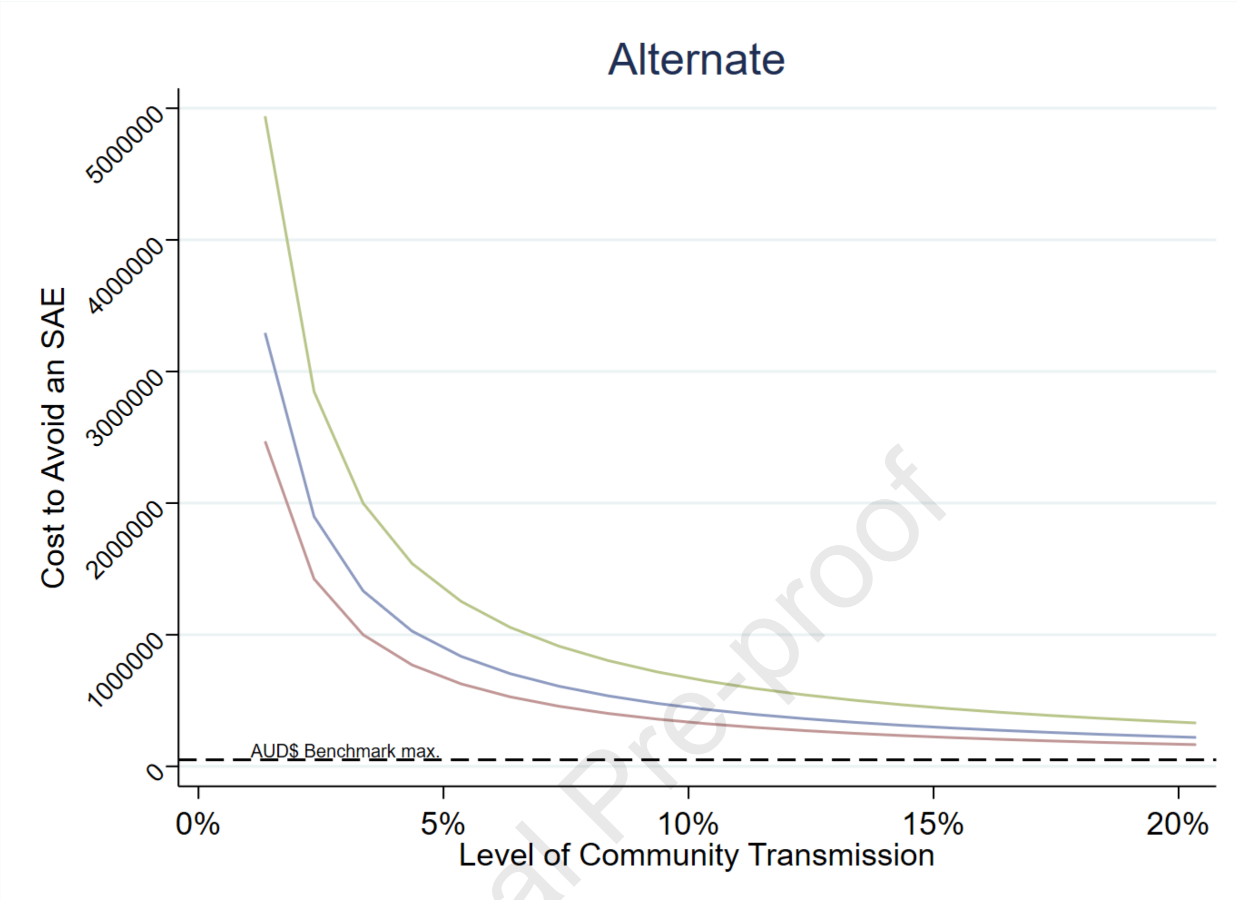
Table 1: Factors influencing the risk of COVID-19 related adverse outcomes for HCW in the endoscopy setting - Australia

Pandemic/Endemic Scenario:	No test, high community transmission, no PPE	Worst case RAT: low test sensitivity and high community transmission	Best case RAT: high test sensitivity and low community transmission	Worst case PCR: high community transmission	Best case PCR: low community transmission	Alternate: PCR, high community transmission, no PPE
Factors						
Test Sensitivity[18,33]	0%	60%	90%	95%	95%	95%
Population infected with SARS-CoV-2	5%	5%	1·36%	5%	1·36%	1·36%
Age adjusted risk of SARS-CoV-2 infection in endoscopy patient population (Age >50 yrs)	15·89%	15·89%	15·89%	15·89%	15·89%	15·89%
Proportion of SARS-CoV-2 cases without symptoms[22]	17%	17%	17%	17%	17%	17%
Transmission Rates						
Risk of infection from asymptomatic carrier compared to symptomatic carrier[22]	58%	58%	58%	58%	58%	58%
Full PPE use (prevents >95% of transmissions)	100%	5%	5%	5%	5%	100%
Risk reduction of infection for vaccinated [30]	95%	95%	95%	95%	95%	95%
Risk reduction for SAE for vaccinated [30]	70%	70%	70%	70%	70%	70%
Endoscopy Staff Exposed per procedure (N)	10	10	10	10	10	10
SAE per 1,000,000 procedures	117.50	2.35	0.159	0.293	0.079	1.598
Cost per test:	-	$10	$10	$100	$100	$100
Cost to avoid 1 COVID-19 staff fatality	-	$86,838·41	$85,217·53	$853,149·26	$851,595·48	$862,749·79


Worst case RAT
Cost to Avoid an SAE
500000
400000
300000
200000
100000
0
AUD$ Benchmark max.
0%
5%
10%
15%
20%
Level of Community Transmission


Best case RAT
Cost to Avoid an SAE
500000
400000
300000
200000
100000
0
AUD$ Benchmark max.
0%
5%
10%
15%
20%
Level of Community Transmission


PCR
Cost to Avoid an SAE
5000000
4000000
3000000
2000000
1000000
0
AUD$ Benchmark max.
0%
5%
10%
15%
20%
Level of Community Transmission


Alternate
Cost to Avoid an SAE
5000000
4000000
3000000
2000000
1000000
0
AUD$ Benchmark max.
0%
5%
10%
15%
20%
Level of Community Transmission

Acronyms & Abbreviations

HCW - Health Care Worker
PCR - Polymerase Chain Reaction
PPE - Personal Protective Equipment
QALY – Quality Adjusted Life Year
RAT - Rapid Antigen Test
RT-PCR – real time Polymerase Chain Reaction
SAE - Serious Adverse Event
TGA - Australian Therapeutic Goods Administration